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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,564	10/10/2001	Alexander Fred Markham	5585-59367	4375

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

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DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,564

Applicant(s)

Markham et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment filed 10/1/2001 has been entered. Following the entry of the amendment, claims 1-42 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, 1-6, 36 and 38-40, claim(s) , drawn to an isolated nucleic acid molecule which hybridizes to a nucleic acid sequence shown in SEQ ID NO:1 and which has at least 75% identity to a nucleic acid sequence shown in SEQ ID NO: 39 and a method of diagnosis via detecting the expression of SEQ ID NO: 1 and its mutation, classified in class 536/435, subclass 22.1/6.

Group II, claim(s) 7, 22 and 41-42, drawn to a polypeptide, encoded by a nucleic acid sequence having at least 75% identity to a nucleic acid sequence shown in SEQ ID NO: 39 classified in class 530, subclass 350.

Group III, claim(s) 1-4 and 7-9, drawn to a delivery vehicle comprising the nucleic acid or the protein, classified in class 536/530, subclass 22.1/350. If this group is elected, the below summarized specie election A or B is also required.

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Group IV, claim(s) 10-11 and 24-25, drawn to an antibody, classified in class 530, subclass 388.1.

Group V, claim(s) 12-13 and 26, drawn to a method for detecting the antibody of claims 10 and 24, classified in class 435, subclass 7.1.

Group VI, claim(s) 14-16 and 18, drawn to a method of treating orofacial clefting via nucleic acid or protein. If this group is elected, the below summarized specie election A or B is also required, classified in class 435, subclass 6/7.1.

Group VII, claim(s) 17, drawn to a pharmaceutical composition comprising the nucleic acid or protein, classified in class 536/530, subclass 22.1/350. If this group is elected, the below summarized specie election A or B is also required.

Group VIII, claim(s) 19-21 and 37, drawn to an isolated nucleic acid molecule which hybridizes to a nucleic acid sequence shown in SEQ ID NO: 3, classified in class 536, subclass 22.1.

Group IX, claim(s) 19-23, drawn to a delivery vehicle comprising the nucleic acid of claim 19 or the protein of claim 22, classified in class 536/530, subclass 22.1/350. If this group is elected, the below summarized specie election C or B is also required.

Group X, 27-32, claim(s) 27-32, drawn to a method of producing a transgenic mammal, classified in class 800, subclass 8.

Group XI, claim(s) 33, drawn to a reporter gene construct based on a promoter region of a gene or an effective part encoded by SEQ ID NO:1, classified in class 536, subclass 22.1.

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Group XII, claim(s) 34, drawn to a method for detection/screening a pharmaceutical or other compound, classified in class 435, subclass 6.

Group XIII, claim(s) 35, drawn to a cloned nucleic acid molecule encoding a tissue repair protein, classified in class 435, subclass 252.3.

2. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is drawn to a first product, nucleic acid sequence and the method of diagnosis by using the nucleic acid sequence of claim 1. The restriction requirement of Group I is followed by the rules of PCT lack of utility in that the product claims is combined with the first method group. The rest of the groups follows the rules of US restriction practice as set forth below.

Group II is product claims which is drawn to a polypeptide which can be used for enzymatic reaction. Group III is product claims drawn to delivery vehicle which can be used in a therapy. Group IV is product claims, drawn to an antibody which can be used in an immuno assay. Group VII is drawn to a pharmaceutical composition which can be used in a therapy. Group VIII is drawn to a nucleic acid sequence which comprises a different nucleic acid sequence from claims 1-4 and which can be used in nucleic acid purification. Group IX is drawn to a delivery vehicle which is different from the delivery vehicle of Group III since it comprises the different nucleic acids or proteins. Group XI is drawn to a reporter gene which can be used in

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gene expression identification. Group XIII is drawn to a cloned nucleic acid molecule encoding a tissue repair protein which can be used for protein expression.

The method groups are Group V, VI, X and XII which involve different operation modes as described in the claims. Therefore, they are different inventions.

Based upon the analysis above, they lack the same special technical features.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. claims 1-4 are drawn to an isolated nucleic acid molecule which hybridizes to a nucleic acid sequence shown in SEQ ID NO:1.

B. claim 7 are drawn to a polypeptide encoded by a nucleic acid sequence having at least 75% identity to a nucleic acid sequence shown in SEQ ID NO: 39.

C. claims 19-21 are drawn to an isolated nucleic acid molecule which hybridizes to a nucleic acid sequence shown in SEQ ID NO: 3.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

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argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic:

In Group II, claims 8-9 are generic.

In Group VI, claims 14-16 and 18 are generic.

In Group VII, claims 17 is generic.

In Group IX, claim 23 is generic.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the

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6. These claims are generic to a plurality of disclosed patentably distinct restriction groups comprising different SEQ ID NOs. Applicant is required under 35 U.S.C. 121 to elect no more than 1 disclosed nucleic acids even though this requirement is traversed.

Should applicant traverse on the ground that some or all of the different nucleic acids are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the nucleic acids to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J.T.
September 21, 2003



ETHAN WHISENANT
PRIMARY EXAMINER